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10/813,203	03/29/2004	Dinah W. Y. Sah	REGEN1610-1	5122

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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Art Unit: 1632

Continuation Sheet (PTOL-303)

Continuation of 3: NOTE:

With regard to Claim 15, the new limitation to “administering to a subject in need thereof” instead of “administering to a mammal” broadens the scope of the claim with regard to the species and further changes the scope of the claim by limiting the subject to one that is “in need thereof.” Accordingly, the new limitations require new search and consideration and therefore the proposed amendment has not been entered.

Continuation of 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

At pages 5-6 of the response, Applicants assert that the transplantation of conditionally-immortalized CNS progenitor cells results in site-specific differentiation. First, site-specific differentiation in a healthy adult or neonatal brain is not predictive of a therapeutic effect in a diseased brain, particularly for degenerative neurological diseases that involve an ongoing pathological process that may affect the fate of transplanted cells in a manner similar to its effect on endogenous neurons, as discussed in the rejection of record. Second, the references cited in the rejection of record teach that even when graft-derived cells integrate normally into the cytoarchitecture of a diseased brain, that normal integration of cells is not predictive of a therapeutic outcome (see especially Milward et al., 1997). Thus, there is no evidence that transplanted cells that differentiate *in vivo* produce a therapeutic effect.

Where Applicant’s arguments rely on the newly submitted evidence, the arguments are moot, as the evidence has not been entered for the reasons noted above in box no. 8.

Therefore, the claims remain rejected for reasons of record.